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## EUROPEAN PATENT APPLICATION

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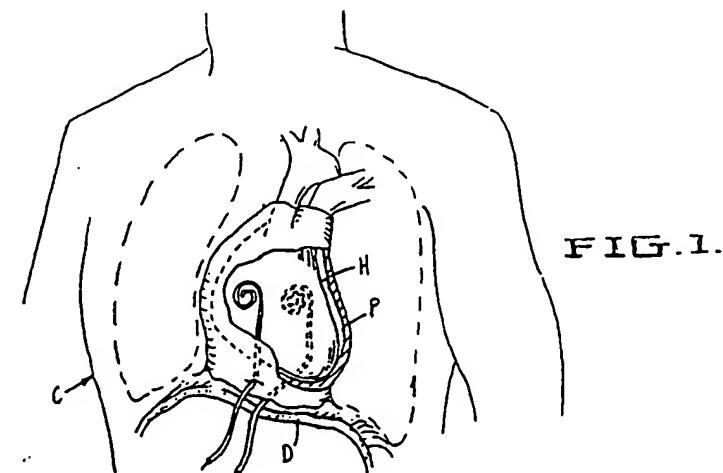
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㉚ Improved method and apparatus for providing intrapericardial access and inserting intrapericardial electrodes.

㉛ Intrapericardial access is provided by clamping the wall of the pericardium between elongate jaw elements carrying axially aligned tubular guides and passing a guide wire through the guides and the pericardial tissue therebetween. In the preferred embodiment the jaw elements include interengageable ratchets for holding the elements in clamping engagement with the wall of the pericardium and

aligned pointed extensions for piercing the pericardial tissue clamped between the elements. Further intrapericardial access is provided by an additional tubular guide carried by the jaw element intended to be disposed in the pericardium during placement of the guide wire.



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Figs. 5 to 15a are cross-sectional side views of the upper region of a human body, sequentially illustrating the steps of practicing the present invention to first access the interior of the pericardium and then place defibrillator electrodes therein;

Fig. 15b is a cross-sectional elevational view, with parts thereof broken away, illustrating a modification of the arrangement shown in Fig. 15a, wherein the electrode within the anterior pericardial space is secured to the pericardium through means of a crimpable button;

Fig. 16 is an exploded perspective view of a first alternative embodiment of the intrapericardial access apparatus;

Fig. 17 is a perspective view of a second alternative embodiment of the intrapericardial access apparatus;

Fig. 18 is a cross-sectional view of the chest region of a human body, illustrating the first alternative embodiment access apparatus in the process of being positioned to extend to either side of the lower wall of the pericardium;

Fig. 19 is a cross-sectional elevational view similar to Fig. 18, illustrating the first alternative embodiment access apparatus in the process of being used to extend a guide wire through the lower wall of the pericardium;

Fig. 20 is a side elevational view of a coiled electrode which may be placed through means of the method and apparatus of the present invention; and,

Fig. 21 is a front elevational view of the Fig. 20 electrode, taken on the plane designated by line 21-21 of Fig. 20.

#### Detailed Description of the Illustrated Embodiments

The chest region of the human body shown in the drawings is designated in its entirety by the letter "C" and is illustrated to show the pericardium "P", the heart "H", the diaphragm "D" and the forward rib cage "R". As shown in Figs. 1 and 2, an electrode "E<sub>1</sub>" is shown posteriorly positioned within the pericardium and electrode "E<sub>2</sub>" is shown anteriorly positioned within the pericardium. The electrodes "E<sub>1</sub>" and "E<sub>2</sub>" shown in Figs. 1 and 2 have been placed through means of the method and apparatus of the present invention. The process for this placement is described in detail in the following discussion.

The curved probe shown in Fig. 3 is designated in its entirety by the numeral 10. This probe is fabricated of a rigid material, such as stainless steel, and finished so as to have a smooth exterior surface. Its purpose, as will become more apparent from the following discussion is to enable a surgeon to dissect a tunnel between the pericard-

ium and diaphragm through a subxiphoid incision formed in the chest wall.

The preferred embodiment intrapericardial access apparatus of Fig. 4 is designated in its entirely by the numeral 12. This apparatus is of a forceps construction embodying upper and lower elongate jaw elements 14 and 16, respectively, similar to those used for tenaculum forceps. The jaw elements are hingedly secured together for movement toward and away from each other by a hinge pin 18. The distal ends of the jaw elements 14 and 16 are formed with rigid aligned lateral extensions 20 and 22, respectively. These extensions, as will become more apparent from the following discussion, are pointed and provided to clampingly engage the tissue of the pericardium therebetween. Handles 24 and 26 are rigidly affixed to the jaw elements 14 and 16, respectively, and terminate in thumb and finger rings. Interengageable ratchet elements 28 and 30 are formed on the handles 24 and 26 to selectively lock the handles in a condition wherein the extensions 20 and 22 are clampingly engaged with pericardial tissue.

A first primary open-ended tubular guide 32 is fixed to and extends over the outer side of the jaw element 14 and terminates in a open distal end 34 extending laterally of the element. A second open-ended tubular guide 36 is fixed to and extends over the jaw element 16 and terminates in an open distal end 38 extending laterally of that element. The ends 34 and 38 are axially aligned when the jaw elements are clampingly engaged with the pericardial tissue and, in the preferred embodiment, are of such relative diameters that the end 38 may fit within the end 34. The edges of the ends may be sharpened to cut through the pericardial tissue upon being clamped into engagement therewith.

A secondary open-ended tubular guide 40 is fixed to and extends along the guide 32. The guide 40 terminates in a bias cut open end short of the distal end 34. The purpose of the secondary lumen is to provide additional access into the interior of the pericardium for the insertion of instruments such as: a secondary guide wire; an irrigation catheter; or a fiberoptic scope.

Figs. 5 to 15a sequentially illustrate the steps of the inventive method in the process of accessing the interior of the pericardium and implanting defibrillator electrodes within the pericardium to the posterior and anterior of the heart. At the outset of the procedure, a subxiphoid incision 42 is formed in the chest wall. The method of the invention is then carried out through the following steps:

1. A pair of clamps or forceps 44 are used to pick up the inferior border of the pericardium "P" through the subxiphoid incision (Fig. 5). This is carried out under direct vision.
2. A curved probe, such as the probe 10 is used

pericardium.

The first alternative embodiment of the access apparatus shown in Fig. 16 is designated in its entirety by the numeral "60". This apparatus comprises: an upper jaw element 62 of an open-ended tubular configuration having an open distal end 64 extending laterally therefrom; a lower jaw element 66 of an open-ended tubular configuration having an open distal end 68 extending laterally therefrom; a T-shaped block 70 fixed to the element 62, said block including a tongue-like extension 72; and, a block 74 fixed to the jaw element 66 and having a socket 76 therein for complimentary receipt of the tongue-like extension 72. The blocks 70 and 74 are so positioned relative to the elements 62 and 66 that the distal ends 64 and 68 assume an axially aligned condition when the extension 72 is received within the socket 76. The element 62 is so proportioned relative to the element 66 that the distal end 64 may be received within the distal end 66 when the extension 72 and groove 76 are complimentally engaged.

The apparatus 60 is used in a manner corresponding to that of the apparatus 12, with the exception that the jaw elements of the apparatus 60 may be inserted into place individually and that the apparatus includes no pointed lateral extensions, such as the extensions 20 and 22. Figs. 18 and 19 show the manner in which the apparatus 60 would be placed to extend a guide wire through the lower wall of the pericardium. It should be appreciated that the guide wire 50 would be provided with a sharpened tip and extended from the upper jaw element 62 through pericardium and into the lower jaw element 66.

The second alternative embodiment apparatus of Fig. 17 is designated in its entirety by the numeral "60<sub>a</sub>". The parts of the apparatus "60<sub>a</sub>" are similar to those of the apparatus "60" and designated by like numerals, followed by the subscript "a" as follows: upper jaw element 62<sub>a</sub>; open distal end 64<sub>a</sub>; lower jaw element 66<sub>a</sub>; open distal end 68<sub>a</sub>; block 70<sub>a</sub>; tongue-like extension 72<sub>a</sub>; block 74<sub>a</sub>; and socket 76<sub>a</sub>. The block 70<sub>a</sub> is pivotally secured to the block 74<sub>a</sub> by a hinge pin 78 and is moveable about this pin between the open condition illustrated in Fig. 17 and a closed condition wherein the distal end 74<sub>a</sub> is received within the distal end 68<sub>a</sub>.

The operation of the apparatus 60<sub>a</sub> corresponds to that of the apparatus 60, with the exception that the surgeon has the option of inserting the apparatus into place as shown in Fig. 18 with the blocks 70<sub>a</sub> and 74<sub>a</sub> hingedly interconnected. Alternatively, he may insert them individually and hingedly secure them together after they are in place.

## CONCLUSION

From the foregoing detailed description, it is believed apparent that the present invention provides a method and apparatus whereby intrapericardial access may be provided with minimal surgery and risk of physical trauma to the heart. It should be understood, however, that the invention is not intended to be limited to the specifics of the described embodiments, but rather is defined by the accompanying claims.

### 15 Claims

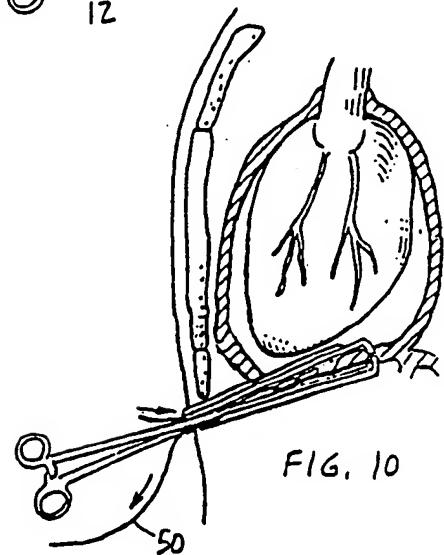
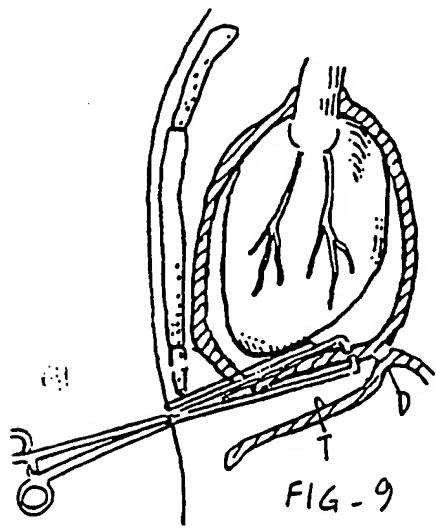
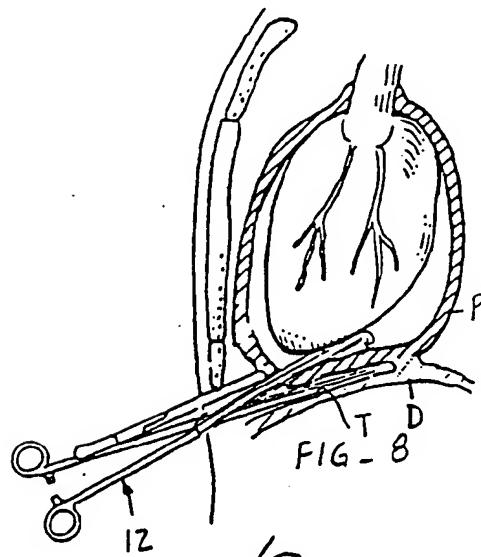
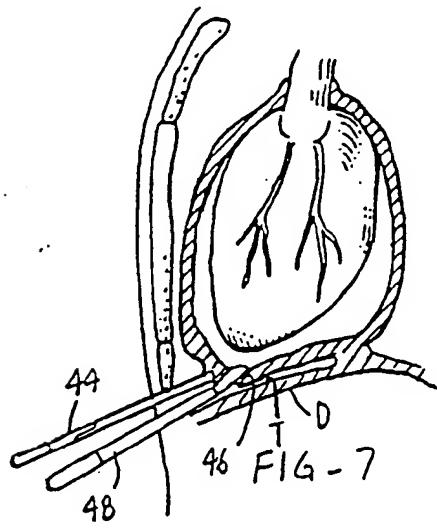
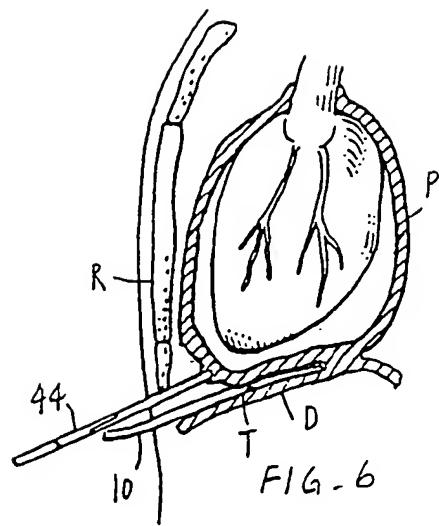
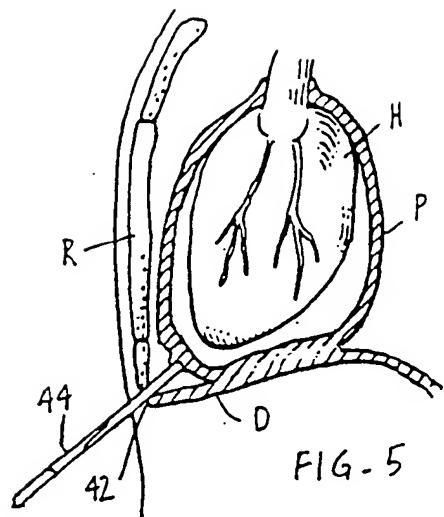
1. A method for implanting an electrode within the interior of the pericardium, comprising the steps of:

- (a) creating a subxiphoid incision;
- (b) dissecting a tunnel between the pericardium and the diaphragm from the subxiphoid incision towards the posterior aspect of the pericardium;
- (c) making a pericardial incision in the inferior border of the pericardium;
- (d) providing a clamp-like placement device having elongate tubular jaws with aligned open distal ends curved toward one another;
- (e) passing one of the jaws through the pericardial incision to locate the curved end of said one jaw at a posterior position within the pericardium;
- (f) passing the other of the jaws into the tunnel to the exterior of the pericardium to locate the curved end of said other jaw in alignment with the curved end of said one jaw;
- (g) passing a guide wire through the jaws to extend the wire within and through the pericardium;
- (h) removing the placement device while leaving the guide wire in place;
- (i) extending a cannula over the wire within the tunnel to pass the cannula through the tunnel and into the pericardium; and,
- (j) passing an electrode through the cannula and into the pericardium to one side of the heart.

2. A method according to Claim 1 wherein the electrode is a first electrode and the cannula through which it is passed is a first cannula; further comprising the steps of extending a second cannula into the pericardium through the pericardial incision and passing a second electrode into the pericardium through the second cannula so as to position said second electrode on the opposite side of the heart from the first electrode.

3. A method according to Claim 2 further comprising the step of fastening the second electrode to the pericardium or the surrounding connective tissue to hold the second electrode in a generally

- jaw elements, said secondary tubular guide extending generally parallel to and terminating short of the distal end of the primary tubular element secured to said one jaw element.
17. Apparatus according to Claim 15 wherein the means for securing the jaw elements together comprises a hinge connection between the elements.
18. Apparatus according to Claim 17, further comprising a handle secured to each jaw element and extending beyond the hinge connection between the elements to facilitate selective movement of the jaw elements toward and away from one other.
19. Apparatus according to Claim 15 wherein one of the jaw elements is adapted to be extended intrapericardially and the other of the jaw elements is adapted to be extended extrapericardially; the apparatus further comprising means for holding the jaw elements with the distal ends of the primary guides aligned in clamping engagement with opposite sides of pericardial tissue therebetween.
20. Apparatus according to Claim 19 further comprising sharpened edges on the distal ends of the primary guides to cut a hole through pericardial tissue upon being clamped into engagement with opposite sides of the tissue.
21. Apparatus according to Claim 18 wherein one of the jaw elements is adapted to be extended intrapericardially and the other of the jaw elements is adapted to be extended extrapericardially; the apparatus further comprising means for holding the jaw elements with the distal ends of the primary guides aligned in clamping engagement with opposite sides of pericardial tissue therebetween.
22. Apparatus according to Claim 20 wherein the means for holding the jaw elements with the distal ends of the primary guides in clamping engagement with pericardial tissue comprises interengageable ratchet elements on the handles.
23. Apparatus according to Claim 15 further comprising a lateral extension on each of the jaw elements, said extensions being disposed to clampingly engage pericardial tissue therebetween when the jaw elements are secured together in the condition with the distal ends of the tubular guides in closely adjacent aligned relationship.
24. Apparatus according to Claim 23 wherein the lateral extensions are disposed closely adjacent the open distal ends of the guides.
25. Apparatus according to Claim 24 further comprising a secondary open ended tubular guide secured to and extending along at least one of at least one of said jaw elements, said secondary tubular guide extending generally parallel to and terminating short of the distal end of the primary tubular element secured to said one jaw element.
26. Apparatus according to Claim 24 wherein the means for securing the jaw elements together comprises a hinge connection between the elements.
27. Apparatus according to Claim 26, further comprising a handle secured to each jaw element and extending beyond the hinge connection between the elements to facilitate selective movement of the jaw elements toward and away from one other.
28. Apparatus according to Claim 27 wherein one of the jaw elements is adapted to be extended intrapericardially and the other of the jaw elements is adapted to be extended extrapericardially; the apparatus further comprising means for holding the jaw elements with the lateral extensions thereof in clamping engagement with opposite sides of pericardial tissue therebetween.
29. Apparatus according to Claim 28 wherein the means for holding the lateral extensions of the jaw elements in clamping engagement with pericardial tissue comprises interengageable ratchet elements on the handles.



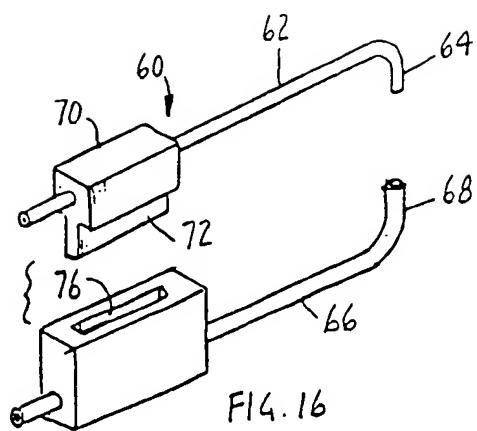


FIG. 16

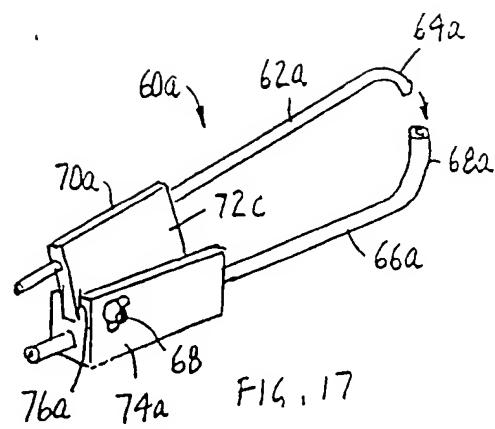


FIG. 17

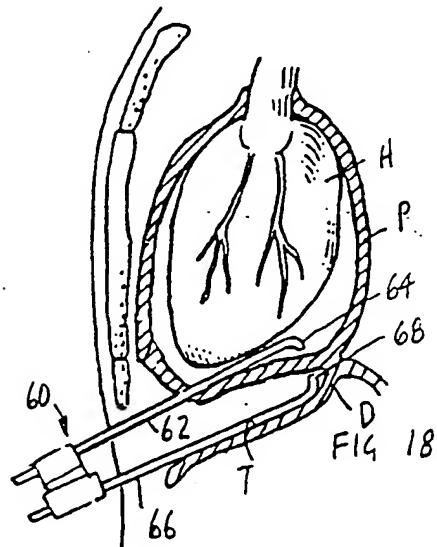


FIG. 18

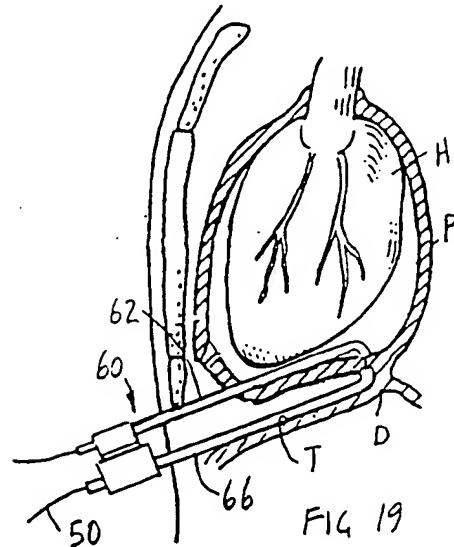


FIG. 19

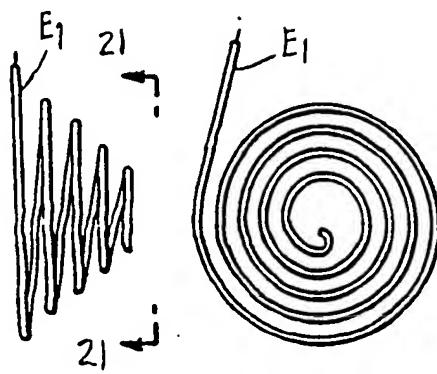


FIG. 20



FIG. 21



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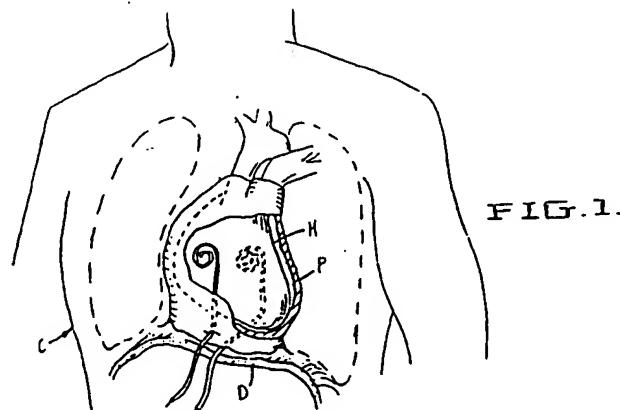
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(54) Improved method and apparatus for providing intrapericardial access and inserting intrapericardial electrodes.

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gagement with the wall of the pericardium and aligned pointed extensions for piercing the pericardial tissue clamped between the elements. Further intrapericardial access is provided by an additional tubular guide carried by the jaw element intended to be disposed in the pericardium during placement of the guide wire.



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Claims not searched: 1-14

Method for treatment of the human or animal body by  
surgery or therapy (see Art 52(4) of the European  
Patent Convention)